

Translation

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PATENT COOPERATION TREATY

PCT/DE2003/004217



PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference T 44328WO/AW/hs	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/DE2003/004217	International filing date (day/month/year) 19 December 2003 (19.12.2003)	Priority date (day/month/year) 23 December 2002 (23.12.2002)
International Patent Classification (IPC) or national classification and IPC C12Q 1/68		
Applicant INDIVUMED GmbH		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 3 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 25 June 2004 (25.06.2004)	Date of completion of this report 21 April 2005 (21.04.2005)
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE2003/004217

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☐ the international application as originally filed
- ☒ the description:  
 pages \_\_\_\_\_ 1-14 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☒ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_ 1-15 \_\_\_\_\_, filed with the letter of \_\_\_\_\_ 16 March 2005 (16.03.2005)
- ☒ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_ 1/1 \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item. These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/DE 03/04217

## V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

### 1. Statement

Novelty (N)	Claims	1-15	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	1-15	NO
Industrial applicability (IA)	Claims	1-15	YES
	Claims		NO

### 2. Citations and explanations

Reference is made to the following documents:

- D1: US-A-5 747 265 (RUGG ARTHUR E et al.), 5 May 1998 (1998-05-05)  
D2: US-A-5 753 444 (COOMBS JANA et al.), 19 May 1998 (1998-05-19)  
D3: KONONEN et al.: "Tissue microarrays for high-throughput molecular profiling of tumour specimens", NATURE MEDICINE, NATURE PUBLISHING, CO, US, Vol. 4, No. 7, July 1998 (1998-07), pages 844-847, XP002160224, ISSN 1078-8956

#### Lack of inventive step (PCT Article 33(3))

The application fails to meet the requirements of PCT Article 33(1) because the subject matter of claims 1 to 15 does not involve an inventive step (PCT Article 33(3)).

The amended claim 1 relates to a method for assembling a collection of isolated human tissue samples. Document D3, which is considered to be the prior art closest to the subject matter of claim 1, also discloses (the references in parentheses are to D3) a method for assembling a collection of isolated human tissue samples (see the abstract). D3 also mentions the advantages of standardised conditions: "*Tissues fixed in a uniform manner provide a substantial advantage compared with variably fixed archival tissues...*" (page 844, right-hand column). The subject matter of claim 1 differs from the known method in that the period (between isolation and preservation) is defined as less than 25 minutes with a maximum deviation of 10%. The technical effect can

be seen in the statistical verification of experimental results (page 2, lines 28 to 33). The problem addressed by the present invention can thus be seen as that of providing a method for assembling a statistically significant collection of samples.

The solution (preservation within a defined period after isolation) is not inventive for the following reasons:

- It is already known from D1 (column 1, lines 54 to 56) that the period between isolation and preservation is important ("*a ... short half life makes the sampling time critical*"). Hence both the problem and its solution (standardisation of the period) were already generally known.
- Claim 1 defines the period as 25 minutes with a maximum deviation of 10%. Figure 1 in the present application shows a change in the protein composition within a matter of minutes. In view of the changes shown in figure 1 (for example, between 15 and 20 minutes, or between 20 and 30 minutes), it is clear that a 10% deviation does not result in a statistically significant collection of samples. Claim 1 therefore fails to solve the problem.

#### Other independent claims

The same line of reasoning applies similarly to independent claim 15. The subject matter of independent claim 15 therefore does not involve an inventive step (PCT Article 33(3)).

#### Dependent claims

Dependent claims 2 to 14 do not contain any features that meet the PCT requirements in respect of novelty and inventive step when combined with the features of any of the back-referenced claims (see documents D1 to D3 and the passages cited in the search report).